REMARKS

Applicant thanks the Examiner and Supervising Examiner for taking the time on October 5, 2004, to discuss the merits of the outstanding office action and the claims. Applicant has amended the claims in the manner proposed during that conversation. Accordingly, reconsideration of the rejections set forth in the office action dated May 17, 2004, is respectfully requested. Applicant has canceled claim 23 without prejudice, and has amended claim 1 to address and overcome the Examiner's objection. No new claims have been added, and the amendments to the existing claims are all supported in the specification. Thus, no new matter has been added by way of this amendment.

Enclosed is a check for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050.

Rejection of Claims Under 35 U.S.C. Section 112

The Examiner rejected claims 1, 35, 37-39, 48, and 60 under 35 U.S.C. Section 112, second paragraph for allegedly being vague and indefinite. Applicant has amended each of these claims to overcome the Examiner's Section 112 rejection thereof. Therefore, favorable action on the merits of these claims is now earnestly solicited.

Rejection of Claims Under 35 U.S.C. Section 102(b)

The Examiner rejected a number of the pending claims under 35 U.S.C. Section 102(b) for allegedly being anticipated by Cui et al. (U.S. 6,576,193), Guirguis et al. (U.S. 6,277,646), or Hudak et al. (U.S. 6,565,808). In response to the Office Action dated October 22, 2003, applicant amended claim 1 to recite a valve, "wherein said valve can be actuated only once." Applicant argued that none of the prior art references teach a specimen collection device having a valve that can be actuated only once. The Examiner disagreed, and stated that the aforementioned references did teach a valve that can be actuated only once. Applicant has now amended claim 1 to clarify that the specimen includes a valve that is inoperable after a first actuation. This feature distinguishes the claimed invention from the references cited thus far, because none of the cited references teaches a specimen collection device having a valve that is inoperable after a first actuation. Accordingly, Applicant respectfully requests that the Examiner withdraw the Section 102(b) rejection of claim 1. Claims 2-43 and 60 depend from claim 1, and

are therefore patentably distinct from the prior art for at least those reasons articulated with respect to claim 1. Also, claims 44-59 are patentably distinct from the prior art for at least the same reasons articulated with respect to claim 1.

Rejection of Claims Under 35 U.S.C. Section 103(a)

The Examiner rejected several of the claims under 35 U.S.C. Section 103(a) as being unpatentable over Cui et al. in view of various other references. Claim 60 was rejected as being unpatentable over Guirguis et al. in view of Pampinella (U.S. 2002/0023482).

Relevant Law

[I]n order to establish a *prima facie* case of obviousness, there must be evidence, preferably a teaching, suggestion, incentive or inference from the cited art or in the form of generally available knowledge that one of ordinary skill would have been led to modify the relevant teaching to arrive at what is claimed. *In re Papesch*, 315 F.2d 381, 391, 137 USPQ 43, 51 (CCPA 1963).

The prior art must provide a motivation whereby one of ordinary skill in the art would have been led to do that which the applicant has done. *Stratoflex Inc. v Aeroquip Corp.*, 713 F.2d 1530, 1535, 218 USPQ 871, 876 (Fed. Cir. 1983). In addition, the mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification. *In re Fritch*, 23 USPQ 1783 (Fed. Cir. 1992).

Argument

Applicant has amended claim 1 to recite a specimen collection device having a valve that is inoperable after a first actuation. None of the references cited thus far, neither alone nor in combination with one another, teach or suggest a specimen collection device having a valve that is inoperable after a first actuation. Furthermore, there is no motivation or suggestion in any of these references to use a valve that is inoperable after a first actuation. Therefore, Applicant respectfully submits that claim 1 as amended herein is patentably distinct from the prior art cited thus far. Claims 2-43 and 60 all depend from claim 1 and are patentable over the prior art for at least those reasons articulated with respect to claim 1. Also, claims 44-59 are patentably distinct from the prior art for at least the same reasons articulated with respect to claim 1.

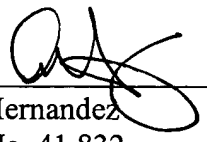
Rejection of Claims 1-20 and 22-59 Under the Judicially Created Doctrine of Obviousness-type Double Patenting

The Examiner provisionally rejected claims 1-20 and 22-59 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-62 of copending Application No. 10/211,199. Since obviousness-type double patenting cannot be assessed until there is allowable subject matter, Applicant respectfully requests deferral of this issue until an indication that there is allowable subject matter in the instant application. Upon review of the claims pending at that time, the need for a Terminal Disclaimer will be assessed, and, if needed, a Terminal Disclaimer will be provided.

Conclusion

Applicant respectfully submits that the pending claims are now in condition for allowance and respectfully requests the same. If the Examiner has any questions regarding the foregoing, he is cordially invited to contact the undersigned so that any such matters may be promptly resolved.

Respectfully submitted,



Fred Hernandez
Reg. No. 41,832

USPTO Customer No.: 20985
Fish & Richardson P.C.
12390 El Camino Real
San Diego, California 92130
Telephone: (858) 678-5625
Facsimile: (202) 626-7796
Email: fhernandez@fr.com